



4164-01-P

## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Food and Drug Administration**

**[Docket No. FDA-2017-D-2834]**

### **Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule; Guidance for Industry; Availability**

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled “Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.” This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, roll-your-own (RYO) tobacco, and cigarette tobacco in complying with the Federal Food, Drug, and Cosmetic Act (the FD&C Act), as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), and FDA regulations.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

#### Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged.

Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see “Written/Paper Submissions” and “Instructions”).

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in “Instructions.”

Instructions: All submissions received must include the Docket No. FDA-2017-D-2834 for “Three-Month Extension of Certain Tobacco Product Compliance Deadlines Announced in the Final Deeming Rule.” Received comments will be placed in the docket and, except for those

submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the

prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of this guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the guidance document may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

FOR FURTHER INFORMATION CONTACT: Deirdre Jurand, Center for Tobacco Products, Food and Drug Administration, 10903 New Hampshire Ave., Document Control Center, Bldg. 71, rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-0002, email: CTPRegulations@fda.hhs.gov.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a guidance for industry entitled “Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule.” This guidance is intended to assist persons who manufacture, package, sell, offer to sell, distribute, or import for sale and distribution within the United States newly regulated tobacco products, RYO tobacco, and cigarette tobacco in complying with the FD&C Act, as amended by the Tobacco Control Act, and FDA regulations. We are issuing this guidance consistent with our good guidance practices (GGP) regulation (§ 10.115 (21 CFR 10.115)). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate given that the 3-month extension applies to provisions

with imminent compliance deadlines (§ 10.115(g)(2)). We made this determination because FDA needs to communicate in a timely manner that the guidance provides a 3-month extension to the compliance deadlines for certain provisions under the final deeming rule that are set for as early as May 2017. Although this guidance document is immediately effective, it remains subject to comment in accordance with FDA’s GGP regulation.

The Tobacco Control Act (Pub. L. 111-31) granted FDA the authority to immediately regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, RYO, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product to be subject to Chapter IX of the FD&C Act (section 901(b) (21 U.S.C. 387a(b)) of the FD&C Act). On May 10, 2016, FDA issued that rule, extending FDA’s tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah, pipe tobacco, nicotine gels, dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (“the final deeming rule”).<sup>1</sup> Chapter IX of the FD&C Act now applies to newly regulated tobacco products, including sections 904(a)(1) and (4) (21 U.S.C.387d(a)(1) and (4)) (ingredient listing, health document submissions), 903(a)(4) and (a)(8) (21 U.S.C. 387c(a)(4) and (a)(8)) (labeling requirements), 904(c)(1), 905(b), (c), (d), (h) (registration), (21 U.S.C. 387e(b), (c), (d), (h)) 905(i)(1) (product listing), 907(a)(1)(B) (21 U.S.C. 387g(a)(1)(B)) (additional special rule), 911 (21 U.S.C. 387k) (modified risk claims), 904(a)(3) and 915 (21 U.S.C. 387o) (harmful and potentially harmful constituent

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<sup>1</sup> “Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products,” 81 FR28974 (May 10, 2016).

reporting), and 920 (21 U.S.C. 387t) (labeling, recordkeeping, records inspection). The final rule also included several requirements that apply to a subgroup of products referred to as “covered tobacco products.”

FDA is providing a 3-month extension that applies to effective dates and compliance deadlines for requirements under the final rule set for May 10, 2017, or later and to all categories of the newly regulated products, as well as the addictiveness warning requirement for RYO and cigarette tobacco.

The guidance represents the current thinking of the FDA on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

## II. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in section 910(c)(1)(A)(i) of the FD&C Act and 21 CFR part 1143 have been approved under OMB control number 0910-0768; the collections of information in section 905(j) of the FD&C Act have been approved under OMB control number 0910-0673; the collections of information in section 904(a)(4) of the FD&C Act have been approved under OMB control number 0910-0654; the collections of information in 21 CFR part 1107 have been approved under OMB control number 0910-0684; the collections of information in section 904(c)(1), 905(b),(c),(d), (h), and 905(i)(1) of the FD&C Act have been approved under OMB control number 0910-0650.

## III. Electronic Access

Persons with access to the Internet may obtain an electronic version of the guidance at either <https://www.regulations.gov> or

<https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: May 10, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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